122921

ATILA BioSystems

iAMP® COVID-19 Detection Kit

REF **iAMP-COVID19-100-CE**

Instructions for Use

V1.0

April, 2020

CE Σ 100

Table of Contents

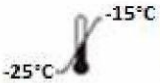
IMPORTANT NOTICE

The instruction for use must be read carefully prior to use and followed accordingly. Reliability of results cannot be guaranteed if there are any deviations from these instructions.

SYMBOLS


Consult instructions for use


In vitro diagnostic medical device



Temperature limit from -25°C to -15°C

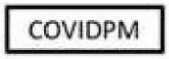
Contains sufficient for 100 tests


Use by

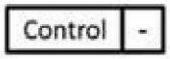
Catalogue number

Batch code

Buffer Mix

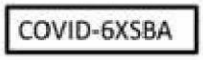


Primer Mix

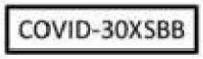


Negative Control

Positive Control



6X Sample Buffer A



30X Sample Buffer B


Manufacturer

Authorized Representative in the European Community

INTENDED USE

iAMP COVID-19 Detection Kit is a real-time fluorescent RT-isothermal assay based on Atila's proprietary isothermal amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs from individuals with signs and symptoms of infection who are suspected of COVID-19.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient's infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The iAMP COVID-19 Detection Kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time nucleic acid amplification and *in vitro* diagnostic procedures.

SUMMARY AND EXPLANATION OF THE TEST

Test Overview

The iAMP COVID-19 Detection Kit is a real-time reverse transcription isothermal amplification test. The test is based on a proprietary isothermal amplification technology termed OMEGA amplification (Patent: WO 2017/205510 A1). OMEGA primer sets are designed to specifically detect RNA and later cDNA from N gene and ORF1ab of the SARS-CoV-2 virus in nasopharyngeal or oropharyngeal swabs from patients with signs and symptoms of infection who are suspected of COVID-19.

Test Principle

The iAMP COVID-19 Detection Kit is intended to detect COVID-19 **directly from raw samples without RNA extraction process. Swab specimens in 1X Sample Buffer Mix with a 15 min incubation at room temperature can be directly used for OMEGA isothermal amplification and signal detection.**

After sample processing, both reverse transcription and nucleic acid amplification take place at 61°C. Target sequence in the specimens is amplified with N/ORF1ab primer sets that are specific to SARS-CoV-2. During the amplification, fluorescence resonance energy transfer (FRET) probes can be incorporated in the amplification products. Upon the incorporation, fluorescence is generated and can be monitored by a fluorescence reader in a real time fashion.

KIT COMPONENTS

1.	Primer Mix (COVIDPM)	540 μL X 1 tube
2.	Buffer Mix (COVIDBM)	540 μL X 1 tube
3.	Positive Control Template (COVIDPC)	300 μL X 1 tube
4.	Negative Control Template (COVIDNC)	300 μL X 1 tube
5.	6X iAMP COVID-19 Sample Buffer A (COVID-6XSBA)	1.25 mL X 5 tubes
6.	30X iAMP COVID-19 Sample Buffer B (COVID-30XSBB)	240 μL X 5 tubes
7.	Instructions for use	1 booklet

EQUIPMENTS & MATERIALS REQUIRED BUT NOT SUPPLIED with the kit

1. iAMP COVID-19 Sample Collection Device (iAMP-COVID19-SCD, Including: synthetic fiber swabs with plastic shafts, and 1.5 mL collection tubes); 100 units needed for one iAMP COVID-19 Detection Kit. Alternatively, synthetic fiber swabs with plastic shafts and 1,5 mL collection tubes can be used.
2. Water: nuclease-free H_2O
3. Surface decontaminants
4. Real-time PCR system with **FAM/HEX** fluorescence channels (Atila PowerGene 9600 Plus Real-Time System, Bio-Rad CFX96 Real-Time System or other compatible instruments)
5. Adjustable pipettes with corresponding filter-plugged pipette tips
6. Disposable powder-free gloves and other personal protective equipment
7. Vortex mixer or equivalent

8. PCR tubes/strips with caps or plate with sealing film
9. PCR tube/plate holder
10. 1.5 mL and 2 mL microcentrifuge tubes and racks
11. Bench top centrifuge for microcentrifuge tubes and PCR tubes/plates

KIT STORAGE INFORMATION

All kit reagents **(COVIDBM, COVIDPM, COVIDNC, COVIDPC, COVID-6XSBA, and COVID-30XSBB)** should be stored at -20°C for long time storage. Shelf life and open kit stability is not available yet. Presumably the shelf-life of the kit is 1 year and the open kit stability is 6 months when kit is properly stored.

SPECIMENS

Biosafety Precautions

Wear appropriate personal protective equipment (e.g. gowns, gloves, masks, eye protection) when working with clinical specimens. Specimen processing should be performed in a certified class II biological safety cabinet following biosafety level 2 or higher guidelines.

Acceptable Specimens

- Direct nasopharyngeal or oropharyngeal dry swabs collected with Atila Sample Collection tube (iAMP-COVID19-SCD*). Alternatively, synthetic fiber swabs with plastic shafts and 1.5mL collection tubes from other vendors can be used.
  ** Not yet available as CE marked product.*

Specimen Handling and Storage

- Use freshly collected specimens for optimal test performance.
- Specimens can be stored at room temperature for up to 12 hours or at 4°C for up to 48 hours after collection and before sample processing.
- If a delay in sample processing is expected, store dry swab specimens at -70°C or lower. Avoid freeze-thaw cycles of the specimens.
- **Processed specimens need to be tested within 2 hours. If a delay in sample testing is expected, store processed specimens at 4 °C for up to 12 hours.**

Specimen Rejection criteria

- Specimens not kept as instructed.
- Incomplete specimen labeling or documentation.
- Inappropriate specimen type.
- Insufficient specimen volume.

QUALITY CONTROL

Due to the sensitivity of iAMP COVID-19 reaction, these assays should be conducted using strict quality control and quality assurance procedures. Following these guidelines will help minimize chance of false-positive or false-negative amplification.

General Considerations

- Personnel must be familiar with the protocol and equipment/instruments used.
- Maintain separate areas and dedicated equipment (e.g. pipettes, microcentrifuges) and supplies (e.g. microcentrifuge tubes, pipette tips, gowns and gloves) for assay reagent setup and handling of processed samples.
- Workflow must always be from the clean area to the dirty area.
- Wear clean disposable gowns and new, previously unworn, powder-free gloves during assay reagent setup and handling of processed samples. Change gloves whenever contamination is suspected.
- Store primer/probes and enzyme master mix at appropriate temperatures (see package insert). Do not use reagents beyond their expiry dates.
- Keep reagent tubes and reactions capped as much as possible.
- Clean and decontaminate surfaces.
- Do not bring processed samples or reaction products into the assay setup area.
- Use aerosol barrier (filter) pipette tips only.

Assay Controls

Assay controls should be tested concurrently with all test samples in each instrumental run.

- COVIDPC - Positive Control Template with an expected threshold cycle (Ct) value range, serves as a control for amplification and detection of SARS-CoV-2 RNA.
- COVIDNC - Negative Control Template, serves to verify that analyte contamination does not occur during reaction setup.

TEST PROCEDURE

Specimen Processing

1. From the kit, take 6X iAMP COVID-19 Sample Buffer A (COVID-6XSBA) and 30X iAMP COVID-19 Sample Buffer B (COVID-30XSBB) out of the freezer. Each tube contains enough volume to process 20 dry swabs. Only thaw the number of COVID-6XSBA and COVID-30XSBB tubes that will be enough for each round of sample processing.
2. Make **1X Sample Buffer Mix** by mixing **(60 x N) µL** 6X iAMP COVID-19 Sample Buffer A and **(12 X N) µL** 30X iAMP COVID-19 Sample Buffer B with **(288 x N) µL** nuclease-free H_2O (N represents the number of dry swab specimens to process). Vortex briefly.
3. Load **350 µL** prepared 1X Sample Buffer Mix into each sample tube. Seal the tube cap securely, vortex and spin briefly.
4. Place the sample tube on the bench for 15 min.

Reaction assembly and run

1. From the kit, take N+2 PCR tubes (N represents number of specimen samples to be tested). Then make **reaction master mix** by adding [**5.2** X (N+2)] µL **PM**, [**5.2** X (N+2)] µL **BM**, and [2.08 X (N+2)] µL 6X iAMP COVID-19 Sample Buffer A with [10.4 X (N+2)] µL nuclease-free H_2O in a 1.5 mL centrifuge tube, gently vortex and spin, and add **22 µL** reaction master mix to

the bottom of each of the PCR tubes.

2. Briefly spin the tubes to bring down the liquid to the bottom of the sample tubes. Add **3 µL** of processed specimen samples (Sample #1 to #N) from step **"Specimen Processing"** to corresponding reaction PCR tubes from **Step 1**. For negative control, add **3 µL** of Negative Control Template into reaction tube #(N+1). For positive control, add **3 µL** of Positive Control Template into reaction tube #(N+2).
3. Cap all the tubes securely. Gently vortex the tubes to mix all the reagents.
4. Briefly spin the tubes in a centrifuge to bring down all the liquid to the bottom of the wells.
5. Set the reaction condition using a compatible real-time PCR machine (All real-time PCR instruments capable of measuring fluorescence in FAM/HEX channel in real-time can be used. Such instruments include but not limited to: Atila PowerGene 9600 Plus Real-Time System, Bio-Rad CFX96 Real-Time PCR Detection System, Roche LightCycler 480 Real-Time PCR System, Applied Biosystems 7500 Real-Time PCR System, etc.)

   PCR program profile:

   1) For denaturation step: set 61°C for 30 seconds
   2) For signal amplification step: run 50 cycles, set 61°C for 1 min for each cycle, while fluorescence reading is taken at the **FAM/HEX** channels at the end of each cycle.

6. Put the reaction tubes into the sample holder and bring into the real-time PCR machine, close the lid, and start the reaction run.

After the run, take out the sample plate and discard them immediately. To avoid contamination **DO NOT OPEN THE REACTION TUBE AFTER THE REACTION**.

AMPLIFICATION RESULT INTERPRETATION

iAMP COVID-19 Detection Kit Controls – Positive, Negative and Internal Controls

- Quality control of a test - every instrument run should include:
  a) **Negative Control Template** - serves to verify that analyte contamination does not occur during reaction setup. There should be NO exponential amplification curve shown in any channel in negative control template, otherwise the test run is invalid.
  b) **Positive Control Template** - serves as a control for amplification and detection of SARS-CoV-2 RNA (ORF1ab and/or N). It should show exponential curves in both channels, and Ct in each channel should be less than 30, otherwise the test run is invalid.

  Quality control of an instrument run should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

- **Internal Control in each specimen** - also serves as a nucleic acid extraction procedural control that validates both the sufficiency of sample collection as well as nucleic extraction procedure and reagent integrity. Internal control is measured in HEX channel in this assay kit. If a sample shows no exponential amplification curve in HEX channel but an exponential curve in FAM channel, the sample is still reported as a valid run and will be interpreted following instructions as below. If there is no exponential amplification curve in any channel in a sample, the sample test result is invalid, and the test must be repeated. If again an invalid

test result is obtained, a new sample of the patient needs to be collected, processed and re-tested.

Examination and Interpretation of Patient Specimen Results

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the specimen results cannot be interpreted.

- **Sample test result interpretation** - an exponential amplification curve showing up at any of the two channels (**FAM/HEX)** indicates the presence of corresponding assayed analyte as indicated below:

	Analyte
FAM Channel	ORF-1ab and/or N
HEX Channel	Sample internal control

A summary of sample test result interpretation is shown as below.

	FAM	**HEX**	**Result**
Case A	-	-	Invalid*
Case B	-	+	SARS-CoV-2 not detected
Case C	+	+ or -	SARS-CoV-2 positive

*: Repeat test. If result remains invalid, re-sampling is needed.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD) – Analytical Sensitivity

The analytical sensitivity of iAMP COVID-19 Detection Kit was determined in Limit of Detection (LoD) studies using Bio-Rad CFX96 Real-Time System, Roche LightCycler Instrument II, and Atila PowerGene 9600 Plus Real-Time System. The iAMP COVID-19 Detection Kit were tested according to the Instructions for Use using SARS-CoV-2 RNA (REF number 102024 from Twist Biosciences) for a tentative LoD study. Oropharyngeal swab collected from healthy individuals were treated with 1x iAMP COVID-19 Sample Buffer Mix. Negative samples were tested by iAMP COVID-19 Detection Kit and confirmed to be negative. Known titer of Twist SARS-CoV-2 RNA was then spiked into the negative oropharyngeal swab specimens to mimic clinical samples and the contrived samples were processed following the IFU of iAMP COVID-19 Detection Kit. The tentative LoD of the assay was determined for swab matrix for each instrument.

Due to the competition in the multiplex assay, amplification of SARS-COV-2 target may delay or totally suppress the internal control signal. Therefore, samples with a positive fluorescence signal for the ORF-1ab/N targets are valid positive even in the absence of the internal control.

Table 1. Tentative LoD studies for Bio-Rad CFX96 Real-Time System.

SARS-CoV-2 - Tentative LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal control Detection Rate
		n	Mean Ct		n	Mean Ct	
2 cp/ µL	5	0	NA	0%	5	23.24	100%
20 cp/ µL	5	5	18.13	100%	4	33.50	80%
200 cp/ µL	5	5	15.55	100%	0	NA	0%
10 cp/ µL	5	3	16.82	60%	5	29.01	100%
20 cp/ µL	5	5	18.13	100%	4	31.23	80%
30 cp/ µL	5	5	17.26	100%	1	41.65	20%
Negative	5	0	NA	0%	5	23.25	100%
Tentative LoD: 20 cp/µL [lowest target level demonstrating >95% detection rate of SARS-COV-2]							

Table 2. Tentative LoD studies for Roche LightCycler Instrument II.

SARS-CoV-2 - Tentative LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal control Detection Rate
		n	Mean Ct		n	Mean Ct	
2 cp/ µL	5	0	NA	0%	5	27.83	100%
20 cp/ µL	5	5	20.50	100%	3	32.38	60%
200 cp/ µL	5	5	16.56	100%	0	NA	0%
10 cp/ µL	5	3	17.33	60%	5	36.58	100%
20 cp/ µL	5	5	17.53	100%	3	26.86	60%
30 cp/ µL	5	5	16.99	100%	0	NA	0%
Negative	6	0	NA	0%	6	27.40	100%
Tentative LoD: 20 cp/µL [lowest target level demonstrating >95% detection rate of SARS-COV-2]							

Table 3. Tentative LoD studies for Atila PowerGene 9600 Plus.

SARS-CoV-2 - Tentative LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal control Detection Rate
		n	Mean Ct		n	Mean Ct	
10 cp/ µL	5	2	19.01	40%	5	20.45	100%
20 cp/ µL	5	5	16.73	100%	4	24.14	80%
30 cp/ µL	5	5	16.02	100%	5	22.76	100%
Tentative LoD: 20 cp/µL [lowest target level demonstrating >95% detection rate of SARS-COV-2]							

Confirmatory LoD studies for Bio-Rad CFX96 Real-Time System, Roche LightCycler Instrument II, and Atila PowerGene 9600 Plus Real-Time System were performed using AccuPlex SARS-CoV-2 Verification Panel from SeraCare (0505-0129). Pseudovirus was spiked into negative oropharyngeal swab specimen at the concentration of 20 copies/µL sample and processed following the IFU of the iAMP COVID-19 Detection Kit.

Table 4. Confirmatory LoD studies for Bio-Rad CFX96 Real-Time System.

SARS-CoV-2 - Confirmatory LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal Control Detection Rate
		n	Mean Ct		n	Mean Ct	
20 cp/µL	20	20	18.45	100%	20	24.63	100%

Table 5. Confirmatory LoD studies for Roche LightCycler Instrument II.

SARS-CoV-2 - Confirmatory LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal Control Detection Rate
		n	Mean Ct		n	Mean Ct	
20 cp/µL	20	20	19.01	100%	14	34.18	70%

Table 6. Confirmatory LoD studies for Atila PowerGene 9600 Plus Real-Time System.

SARS-CoV-2 - Confirmatory LoD							
Target Level	Valid results	SARS-CoV-2 (N/ORF) Positive		SARS-CoV-2 (N/ORF) Detection Rate	Internal Control Positive		Internal Control Detection Rate
		n	Mean Ct		n	Mean Ct	
20 cp/µL	20	20	16.93	100%	14	22.05	70%

20 replicates were tested, and positive results were obtained in all 20 replicates for all three machines. Therefore, the LoD of iAMP COVID-19 Detection Kit is 20 copies/µL sample for the Bio-Rad CFX96 Real-Time System, Roche LightCycler Instrument II, and Atila PowerGene 9600 Plus Real-Time System.

Inclusivity

All primer-annealing regions in both ORF-1ab and N were analyzed *in silico* using NCBI BLASTn,and showed 100% match to all of the published SARS-CoV-2 complete genome sequences from Genbank (n=154 as of March 21, 2020). The iAMP COVID-19 Detection Kit is therefore predicted to detect all currently circulating strains for SARS-CoV-2.

Cross-Reactivity (Analytical Specificity)

The list of organisms shown below has been analyzed *in silico* for potential cross-reactivity with the primers or probe sequences in the iAMP COVID-19 test. There were no primers and probes in the iAMP COVID-19 Detection Kit with homology ≥ 80% with other species and therefore cross reactivity with the organisms below is not expected.

Organisms tested in *in silico* Cross-Reactivity analysis			
Pathogen	**GenBank Acc#**	**Pathogen**	**GenBank Acc#**
Human coronavirus 229E	NC_002645.1	Human parainfluenza virus 4a isolate HPIV4_DK(459)	KF483663.1
Human coronavirus OC43 strain ATCC VR-759	NC_006213.1	Human parainfluenza virus 4b strain 04-13	JQ241176.1
Human coronavirus HKU1	NC_006577.2	Influenza B B/Illinois/13/2005 segment 7	CY019500.1
Human coronavirus NL63	NC_005831.2	Human enterovirus 68 isolate NZ-2010-541	JX070222.1
SARS coronavirus B093	AY686864	Respiratory syncytial virus	NC_001803

MERS coronavirus isolate NL140422	MG021452.1	Human rhinovirus B3 strain SC2606	KY967365.1
Human metapneumovirus (hMPV) isolate 00-1	NC_039199	*Chlamydia pneumoniae* TW-183	NC_005043.1
Human parainfluenza virus 1 isolate NM001	KX639498.1	*Bordetella pertussis* strain B3921	CP011448.1
Human parainfluenza virus 2 isolate VIROAF10	KM190939.1	*Pseudomonas aeruginosa* UCBPP-PA14	CP000438.1
Human parainfluenza virus 3 strain HPIV3/AUS/3/2007	KF530243.1	*Streptococcus salivarius* CCHSS3	FR873481.1

In addition, the organisms listed in the table below were wet-tested. Oropharyngeal swab collected from healthy individuals were treated with 1x iAMP COVID-19 Sample Buffer Mix. Then purified genome DNA/RNA spiked into the negative oropharyngeal swab specimen at the concentration of 10^5 genome copies/µL sample. Samples were processed following the IFU. Three replicates were tested for each organism. No false positive signal was observed in FAM channel (which SARS-CoV-2 is assigned) for any of the replicates when testing with the iAMP COVID-19 Detection Kit, whereas amplification curves for the internal control in the HEX channel showed up as expected. No cross reactivity was observed with the organisms below at the tested concentration.

Organisms wet-tested in swab matrix	**SARS-CoV-2 (N/ORF) Detection Rate**
Human adenovirus 5 (ATCC VR-1516)	0% (0/3)
Influenza A (H1N1)	0% (0/3)
Haemophilus influenzae	0% (0/3)
Legionella pneumophila	0% (0/3)
Mycobacterium tuberculosis	0% (0/3)
Streptococcus pneumoniae	0% (0/3)
Streptococcus pyogenes	0% (0/3)
Mycoplasma pneumoniae	0% (0/3)
Pneumocystis jirovecii (PJP)	0% (0/3)
Candida albicans	0% (0/3)

Endogenous Interference Substances Studies

Interfering substances studies were performed for iAMP COVID-19 Detection Kit. Oropharyngeal swab collected from healthy individuals were treated with 1x iAMP COVID-19 Sample Buffer Mix. Then Synthetic SARS-CoV-2 RNA (REF number 102024 Twist BioSciences) was spiked into the negative oropharyngeal swab specimens at the concentration of 2.5X LoD (50 copies/µL sample). The potentially interfering substances indicated in the table below were added to the positive contrived samples at the indicated concentration, and the samples were processed following IFU. Each substance was also added to the negative oropharyngeal swab specimen to test potential false positives. Each substance was tested in three replicates for positive contrived samples and three replicates for negative swab specimens. Results indicate that iAMP COVID-19 can well tolerate all the substances at the concentration equal or lower than the indicated values without significant interference. Neither false positive nor false negative was observed.

Potential Interfering Substance	Conc.	Positive Samples		Negative Samples
		Viral Strain Level	Results	Results
Mucin: bovine submaxillary gland, type I-S	2.5 mg/ml	2.5X LoD	3/3	0/3
Blood (human)	2.5% v/v	2.5X LoD	3/3	0/3
Afrin Original nasal spray	15% v/v	2.5X LoD	3/3	0/3
Basic Care allergy relief nasal spray (Gluococorticoid)	5% v/v	2.5X LoD	3/3	0/3
NeilMed Nasal gel	1.25%	2.5X LoD	3/3	0/3
GoodSense All Day Allergy, Cetirizine HCl Tablets 10 mg	1 mg/mL	2.5X LoD	3/3	0/3
Cepacol Sore Throat (benzocaine/menthol lozenges)	5 mg/mL	2.5X LoD	3/3	0/3
Zanamivir	3.3 mg/mL	2.5X LoD	3/3	0/3
Tamiflu	2.2 µg/mL	2.5X LoD	3/3	0/3
Mupirocin ointment	5 mg/mL	2.5X LoD	3/3	0/3
tobramycin	4 ug/mL	2.5X LoD	3/3	0/3

Clinical Evaluation

Clinical performance evaluation for the iAMP COVID-19 Detection Kit was performed using the AccuPlex SARS-CoV-2 Verification Panel from SeraCare (0505-0129) and the Bio-Rad CFX96 Real-Time System. Oropharyngeal swab collected from healthy individuals were treated with 1x iAMP COVID-19 Sample Buffer Mix. Pseudovirus was spiked into the first aliquot of negative oropharyngeal swab specimen so that positive contrived samples were generated at the concentration of 40 copies/ µL sample (2X LoD; 20 samples), 100 copies/µL sample (5X LoD; 10 samples), and 200 copies/ µL sample (10X LoD; 5 samples). In addition, the second aliquot of the negative oropharyngeal swabs was spiked with negative control material provided by SeraCare. All samples were processed following IFU of the kit.

Clinical Evaluation of iAMP COVID-19 Detection Kit							
Target Level	**Valid results**	**SARS-CoV-2 (N/ORF) Positive**		**SARS-CoV-2 (N/ORF) Detection Rate**	**Internal Control Positive**		**Internal control Detection Rate**
		n	**Mean Ct**		**n**	**Mean Ct**	
Negative	64	0	NA	0%	64	24.51	100%
2 X LoD	20	20	17.50	100%	20	25.23	100%
5 X LoD	10	10	15.90	100%	0	NA	0%
10 X LoD	5	5	16.06	100%	0	NA	0%

ATILA BioSystems
740 Sierra Vista Ave, Suite E
Mountain View, CA 94043, USA

Tel: +1 (650)-968-8848
Email: info@atilabiosystems.com

EC REP
Fujirebio Europe N.V.
Technologiepark 6, 9052 Gent, Belgium
✆ +32-9 329 13 29